K062001

DEC - 7 2006

VII **510K SUMMARY**

Device Name: Rostam Scented and Unscented Plastic Applicator Tampons (Various Trade Tampons Sold Under Private Labels As Plastic *Applicators)*

Legally marketed device: These Tampons are substantially equivalent to legally marketed Rostam Scented and unscented Tampons with plastic applicators.

Device description: Rostam plastic applicator tampons are menstrual tampons used to absorb menstrual fluid. These Tampons will be provided as two absorbencies, slender regular and light.

These Tampons are made from rayon and/or cotton, polymeric overwrap and cotton cord.

The materials used in these tampons are similar to those used in other legally marketed tampons.

Intended Use: These tampons are menstrual tampons that are inserted into the vagina and used to absorb menstrual fluid.

Assessment of Performance Standards: Not Applicable

Non-Clinical Testing: Biocompatibility testing and safety evaluations of tampon components were historically carried out. The results of these tests demonstrate that these Tampons are equivalent in terms of safety and effectiveness to legally marketed tampons. Standard Syngyna testing confirmed the absorbency of these Tampons. In addition to the review of existing toxicological data in the public literature, the following tests were conducted and are relevant to the safety of Rostam plastic applicator tampons.

◊ **Repeated Insult Patch Test, 100 human subjects**

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Rostam, Ltd.
c/o Robert J. Staab, Ph.D.
DABT, RAC
RTA, Inc.
73 Franklin Tpk.
ALLENDALE NJ 07401

DEC - 7 2006

Re: K062001
Trade/Device Name: Rostam Ltd. Scented and Unscented Plastic Applicator Tampons
Regulation Number: 21 CFR §884.5460
Regulation Name: Scented or scented deodorized menstrual tampon
Product Code: HIL
Regulation Number: 21 CFR §884.5470
Regulation Name: Unscented menstrual tampon
Product Code: HEB
Regulatory Class: II
Dated: October 30, 2006
Received: October 31, 2006

Dear Dr. Staab:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

U.S. Food and Drug Administration

CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

Department of Health and Human Services

Indications for Use

510(k) Number (if known): K062001

Device Name: Trade Name: Rostam Ltd Scented and Unscented Plastic Applicator Tampons

Indications for Use:

Rostam Ltd. Fragranced and Unfragranced plastic applicator tampons are a plug of Cellulosic or synthetic material that is inserted into the vagina and used to absorb menstrual or other vaginal discharge

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _X_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

Center for Devices and Radiological Health / CDRH

David A. Segraves

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K062001